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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,652	11/25/2003	Glenn R. Gibson	N-32809A	7110

1095 7590 02/12/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
BARHAM, BETHANY P	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,652	GIBSON ET AL.	
	Examiner	Art Unit	
	Bethany P. Barham	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-8,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-8,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Receipt is acknowledged of the Applicants' Response and Amended Claims filed on 07/31/2006. Claims 2, 4, and 9 are cancelled. Claims 18-25 remain cancelled without traverse. Claims 1, 3, 5-8 and 10-11 are pending in this action. Claims 1, 3, 5-8 and 10-11 are rejected.

As a result of Applicants' amended claims, the 35 USC §102 rejections of Moro et al, Boehm et al and Rigo et al over Claims 1, 3, 5, 8 and 10 are withdrawn. And 35 USC §103 rejections drawn to claims 2, 4 and 9 are rendered moot as the claims are cancelled.

Failure to Comply with Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. See pages 17-18 of the specification and the Notice to Comply.

Applicant is given THREE MONTHS from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the

extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lesens et al US 6,399,124 B1.

Lesens et al teaches the limitations of claims 1, 3 and 5:

- Lesens et al teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream for the treatment and/or prevention of gastrointestinal disorders, for strengthening the immune system, or for increasing the absorption of minerals (abstract).

- Lesens et al teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen for example from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xylo oligosaccharides, etc (col. 4, lines 44-47; and claim 2). The preferred galacto-oligosaccharides comprise a saccharide part consisting of 2 to 5 repeating units and preferred fructooligosaccharides are inulin-oligofructoses extracted from chicory which may comprise, for example, 1-9 repeating units (col. 4, lines 56-64; and claim 26). Examples 1, 4 and 5 specifically teach edible compositions, coatings and decorations containing galactooligosaccharide P7L, Raftilose L30 and Actilight 950P.
- The composition of Lesens et al teaches that the quantity of fibers in the dessert may contain from 0.1 to 20% of such fibers (by weight relative to dry matter content), and that a single dessert may be designed to provide up to a maximum of 10 g of fiber per dessert (col. 5, lines 15-25).
- Examples 4-5 of Lesens et al teach a cone made of Raftilose L30 (Table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). Such a ratio would yield a weight ratio of 1.56 FOS:GOS in the single food composition.
- Example 4 teaches 1.1 g fibers are provided per ice cream cone, while Example 6 teaches 2.1 g of fiber from the sandwich. Claim 9 of Lesens et al teaches that about 0.1 to about 10% of the frozen dessert comprises fibers.

Lesens et al teaches the limitations of claims 6-8 and 11:

- Lesens et al teaches compositions wherein the edible support alone comprises between about 1 to about 60% milk, between about 0.5 to about 5% of animal or vegetable proteins, between about 0.1 to about 10% fibers, between about 15% to about 30% sucrose and between about 2% to about 20% fat, by weight (claim 9). Examples 1 and 2 teach that a consumption of 200 mL or 100 g of ice cream per day provides proper dietary supplement. And it is the examiners position that all examples of Lesens et al are compositions that are ready-for-consumption and high in calories.

Lesens et al anticipates the instant applications claims 1, 3, 5-8 and 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesens et al US 6,399,124 B1.

Lesens et al teach the limitations of claims 1, 5, and 10:

- Lesens is taught above and claims 1 and 5 are taught above.
- Lesens et al teaches compositions wherein the edible support alone comprises between about 1 to about 60% milk, between about 0.5 to about 5% of animal or vegetable proteins, between about 0.1 to about 10% fibers, between about 15% to about 30% sucrose and between about 2% to about 20% fat, by weight (claim 9). But examples 4-6 also teach compositions comprising flour, which provides a significant amount of carbohydrates (52g - 62g flour/100g total weight).
- Lesens et al does not teach a composition of claim 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Lesens et al to make a composition of FOS, GOS, proteins, carbohydrates, and fats, and one of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges. As stated in MPEP 2144.05: *"[W] here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."*

Claims 1, 3, 5, 7-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al and Boehm et al and Rigo et al in view of Lesens et al US 6,399,124 B1.

Moro et al and Boehm et al and Rigo et al in view of Lesens et al teach the limitations of claims 1, 3, 5, 7-8, and 10-11:

- Moro et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See pages 291, 294 and Table 1). According to Moro et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page 292). This satisfies the weight ratio of FOSCGOS of about 0.01 to about 50. According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation. As formulated, it is the examiner's position that the formula advanced by Moro et al. is both "nutritionally complete" and "ready-for-consumption."
- Boehm et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See page F179 and Table 1). According to Boehm et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page F178). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation. As formulated, it is the examiner's position that the formula advanced by Boehm et al. is both "nutritionally complete" and "ready-for- consumption."

- Moro et al and Boehm et al do not teach a composition comprising more than about 1 g of protein in 100 kcal of claim 7.
- Rigo et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See Table 1). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation, and over 1% of protein can be present per 100 kcal. As formulated, it is the examiner's position that the formula advanced by Rigo et al. is both "nutritionally complete" and "ready-for- consumption."
- Moro et al, Boehm et al, and Rigo et al do not teach the exact percentages of ingredients and ratio of GOS to FOS as claimed.
- Lesens et al is taught above. Lesens teaches the ratio and percentages.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Moro et al and Boehm et al and Rigo et al in view of Lesens to make an composition comprising a mixture of prebiotic fibers such as FOS and GOS, and other ingredients for consumption. One of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges to treat those with gastrointestinal disorders, to promote the growth, in the intestinal tract, of the lactic acid bacteria, also for strengthening the immune system, or for increasing the absorption of minerals. As stated in MPEP 2144.05: *"[W] here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable*

ranges by routine experimentation." Because the exact formulation and portion of a baby formula, nutritional supplement, or other edible composition is determined by age, size, health, and other variables it would be reasonable for one of ordinary skill in the art to experiment and optimize the values set forth in Moro et al and Boehm et al and Rigo et al in view of Lesens et al in order to obtain a composition capable of delivering the appropriate amount of nutrients to the patient.

Response to Arguments

Applicant's arguments with respect to claims 8-12 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

B.P. Barham
Examiner 1615

Notice to Comply	Application No. 10/721,652	Applicant(s) GIBSON ET AL.	
	Examiner Bethany P Barham	Art Unit 1615	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Sequence listing on page 17-18 of specification

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
PatentIn Software Program Support
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